DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	2/23/2026-2/25/2026 FEI NUMBER 3004161528

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert J. de la Haba Jr., Owner, President

FIRM NAME	STREET ADDRESS
Visionary Medical Supplies Inc.	6441 Enterprise Ln Ste 204
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Madison, WI 53719-1163	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The quality management system effectiveness was not maintained in accordance with applicable regulatory requirements.

Specifically, your firm's quality management system has not been effectively implemented and maintained prior to FDA's announced inspection on 02/09/2026 to ensure the safety and effectiveness of your Class I and Class II medical devices. For example:

(A)Your firm's Management Review Procedure, SOP-5.1, Rev 0 was established on 02/16/2026, approximately one week after the announced inspection on 02/09/2026. Since the last management review in 2021, there were no management reviews conducted prior to procedure establishment date.

(B)Your firm did not follow its own procedure in Manual for the Quality System, Rev 25, effective 11/19/2021, to ensure that quality objectives are being accomplished. Your firm has a quality plan for 2026 but did not have quality plans or other documentation before 2026 to show that quality objectives were being achieved prior to the announced inspection on 02/09/2026.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shawn Choi, Investigator X Shawn Choi Investigator Signed By: 2004265134 Date Signed: 02-25-2026 12:43:46	2/25/2026

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X Shawn Choi
Investigator
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Annotations to Observations

Observation 1: Promised to correct

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."